UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Note to Reader

Background: As part of its effort to involve the public in the implementation of the Food Quality Protection Act of 1996 (FQPA), which is designed to ensure that the United States continues to have the safest and most abundant food supply. EPA is undertaking an effort to open public dockets on the organophosphate pesticides. These dockets will make available to all interested parties documents that were developed as part of the U.S. Environmental Protection Agency's process for making reregistration eligibility decisions and tolerance reassessments consistent with FQPA. The dockets include preliminary health assessments and, where available, ecological risk assessments conducted by EPA, rebuttals or corrections to the risk assessments submitted by chemical registrants, and the Agency's response to the registrants' submissions.

The analyses contained in this docket are preliminary in nature and represent the information available to EPA at the time they were prepared. Additional information may have been submitted to EPA which has not yet been incorporated into these analyses, and registrants or others may be developing relevant information. It's common and appropriate that new information and analyses will be used to revise and refine the evaluations contained in these dockets to make them more comprehensive and realistic. The Agency cautions against premature conclusions based on these preliminary assessments and against any use of information contained in these documents out of their full context. Throughout this process, If unacceptable risks are identified, EPA will act to reduce or eliminate the risks.

There is a 60 day comment period in which the public and all interested parties are invited to submit comments on the information in this docket. Comments should directly relate to this organophosphate and to the information and issues available in the information docket. Once the comment period closes, EPA will review all comments and revise the risk assessments, as necessary.

These preliminary risk assessments represent an early stage in the process by which EPA is evaluating the regulatory requirements applicable to existing pesticides. Through this opportunity for notice and comment, the Agency hopes to advance the openness and scientific soundness underpinning its decisions. This process is designed to assure that America continues to enjoy the safest and most abundant food supply. Through implementation of EPA's tolerance reassessment program under the Food Quality Protection Act, the food supply will become even safer. Leading health experts recommend that all people eat a wide variety of foods, including at least five servings of fruits and vegetables a day.

Note: This sheet is provided to help the reader understand how refined and developed the pesticide file is as of the date prepared, what if any changes have occurred recently, and what new information, if any, is expected to be included in the analysis before decisions are made. **It is not meant to be a summary of all current information regarding the chemical.** Rather, the sheet provides some context to better understand the substantive material in the docket (RED chapters, registrant rebuttals, Agency responses to rebuttals, etc.) for this pesticide.

Further, in some cases, differences may be noted between the RED chapters and the Agency's comprehensive reports on the hazard identification information and safety factors for all organophosphates. In these cases, information in the comprehensive reports is the most current and will, barring the submission of more data that the Agency finds useful, be used in the risk assessments.

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May 19, 1999

MEMORANDUM

Subject: Fenitrothion HED RED Chapter; Revised Risk Assessment; PC Code 105901, Case No. 0445; DP Barcode D256052

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This memorandum and attachments update the HED RED Chapter for Fenitrothion (John C. Redden, 5/7/94) taking into consideration requirements of the 1996 Food Quality Protection Act (FQPA). Attachments include the original HED RED Chapter (attachment 1), the most recent Hazard Identification Review Committee (HIARC) report (attachment 2, Jess Rowland, 10/8/97, and 2/19/98 addendum), the most recent dietary risk analysis (attachment 3, Christina Swartz, 5/19/99), the most recent anticipated residue memorandum (attachment 4, Christine Olinger, 5/19/99), the most recent risk assessment revision (attachment 5, Michael Metzger, 2/28/99) and wheat gluten production information (attachment 6, Frank Hernandez 4/28/99). The Agency RED for fenitrothion was issued June 1995.

Background

Fenitrothion is an organothiophosphate insecticide/acaricide. Cumulative risk assessment considering risks from other pesticides which have a common mechanism of toxicity is not addressed in this document.

Following the issuance of the initial HED RED Chapter, all uses of fenitrothion were canceled except EPA Reg. Nos. 506-174 and 506-175, which are ant and roach bait traps, respectively. Additionally, the tolerance established to cover imported wheat gluten remains in effect (15 ppm, 40 CFR 185.2200). Only these uses are considered in this update. Considering only these uses, risk estimates resulting from exposure to fenitrothion are expected to be insignificant as detailed below.

Hazard Characterization

Fenitrothion is an organothiophosphate insecticide/acaricide. The technical material is acutely toxic with category 2 for oral, dermal, and inhalation toxicity, as well as for eye and dermal irritation. The predominant effect of this chemical is cholinesterase inhibition and the clinical signs and toxicity associated with this inhibition. Therefore the toxicity endpoints for risk assessment for fenitrothion are based on the cholinesterase inhibition and other findings associated with it. Developmental toxicity was observed in the rat, but only at doses at which significant maternal toxicity was observed; no developmental effects were observed in the rabbit developmental study. No evidence of carcinogenicity was seen in the mouse and rat carcinogenicity study.

The HED Hazard Identification Committee (HIARC) met on 10/8/97 to examine the hazard data base for fenitrothion considering the requirements of the 1996 Food Quality Protection Act (FQPA) (Jess Rowland, 10/8/97, attached). The committee examined the results of acute delayed, acute, and subchronic neurotoxicity studies, rat and rabbit developmental studies, and a two-generation rat reproduction study. The committee drew two major conclusions: that a developmental neurotoxicity study is not required, and that the hazard data indicate that the FQPA 10X factor should be removed (set to 1X). Regarding the need for a developmental neurotoxicity study, the committee concluded that since no neuropathology was observed in any of the three neurotoxicity studies available, and since no increased susceptibility was observed for fetuses or pups in the developmental and reproduction studies, sufficient information is available to characterize the hazard to infants and children; therefore, a developmental neurotoxicity study is not needed. The decision to remove the 10X factor relative to hazard considerations was made based on having a complete toxicity data base which allowed reasonable understanding in predicting possible effects on infants and children, and the lack of increased susceptibility in the fetuses and/or pups in the developmental and reproduction studies. The decision to remove the FQPA safety factor was confirmed when the Hazard Identification Assessment Review Committee and the FQPA Committee revisited all the organophosphate pesticides as group (J. Rowland and B. Tarplee 8/6/98).

The population adjusted dose (PAD) is a modification of the acute RfD or chronic RfD to

accommodate the FQPA Safety Factor, and is equal to the acute or chronic RfD divided by the FQPA Safety Factor. Since the HED FQPA Safety Factor Committee recommended removal of the 10X Safety Factor, the RfD is identical to the PAD. A summary of the toxicological endpoints and doses selected for risk assessment may be found in Table 1.

Table 1. Doses and Toxicological Endpoints Selected for Fenitrothion

EXPOSURE SCENARIO	DOSE (mg/kg/day)	ENDPOINT	STUDY
Acute Dietary	NOAEL = 12.5	Effects on FOB parameters	Acute Neurotoxicity-Rat
	UF = 100 [FQPA UF = 1]	**Acute RfD = 0.13 mg/kg/day** FQPA population adjusted dose = 0.13 mg/kg/day	
Chronic Dietary	NOAEL = 0.13	Plasma cholinesterase inhibition and histopathology	Chronic Toxicity -Rat
	UF = 100 [FQPA UF = 1]	**Chronic RfD = 0.0013 mg/kg/day** FQPA population adjusted dose = 0.0013 mg/kg/day	

Dietary Assessment

As described in the original HED RED Chapter, a tolerance level of 15 ppm was established to cover residues of fenitrothion in wheat gluten imported from Australia. HED has re-evaluated the magnitude of residue database for fenitrothion and has concluded that the tolerance value for fenitrothion in wheat gluten can be lowered to 3 ppm. Residues in four trials from four different states in Australia resulted in residues ranging from 0.95 to 2.5 ppm in/on wheat gluten; the average residue was 1.84 ppm. Monitoring data from a commercial wheat gluten processing facility in Australia showed residues ranging from 0.09 to 0.9 ppm, with an average of 0.38 ppm. FDA has monitored just a few wheat gluten samples from Australia over the last several years; most samples showed non-detectable residues of fenitrothion, although trace residues (residues less than the level which can be reliably quantified) were found in two samples.

The DEEM™ software which HED uses to evaluate dietary risk does not contain consumption values for wheat gluten. Therefore, in order to estimate dietary exposure to fenitrothion residues in wheat gluten, HED used wheat flour consumption data and calculated an adjustment factor based on wheat gluten availability relative to wheat flour. BEAD estimated the amount of wheat gluten available for consumption as 250 million pounds per year. HED obtained a value for wheat flour from the USDA Economic Research Service Wheat Yearbook for 1997; the total amount of wheat flour available for consumption (subtracting what is available for export) is 40,107 million pounds. This results in a relative ratio of 0.0062, which was then used as an adjustment factor when estimating the dietary exposure to fenitrothion residues.

BEAD has determined that 65 million pounds of wheat gluten are imported from Australia each

year, according to quotas that were created in 1998. Based on that figure, the maximum amount of wheat gluten which could be treated with fenitrothion would be 26% (F. Hernandez, 4/28/99). Note that this assumes that 100% of wheat gluten imported from Australia has been treated.

A chronic dietary risk analysis was conducted for fenitrothion three ways: 1) using the existing tolerance without correction for percent imported from Australia; 2) using the recommendation for a reassessed tolerance without correction for percent imported from Australia; and 3) using anticipated residues calculated from an average residue value and percent imported from Australia. Results of these analyses for the U.S. population and the most highly exposed sub-groups are presented in Table 2.

There is a degree of uncertainty with these risk estimates as they are based on estimated wheat gluten consumption values. These values assume the same proportion of wheat gluten to wheat flour consumption for all population groups, and that this proportion is based on amount available for consumption. Although there is a relatively high uncertainty with this assessment, the risk estimates are so low, HED is confident that there are no chronic dietary risk concerns for fenitrothion in wheat gluten.

Table 2. Estimates of Chronic Dietary Risk for Fenitrothion

Population Group	Percent of Chronic PAD		
	Using Existing Tolerance of 15 ppm	Using Reassessed Tolerance of 3 ppm	Using Anticipated Residues
U.S. Population	9.9	2.0	0.3
Non-Nursing Infants	4.5	0.9	0.1
Children 1 - 6	23	4.6	0.7
Children 7 - 12	16	3.2	0.5
Males 13 - 19	11	2.3	0.4

Although an acute dietary endpoint and NOAEL were identified for fenitrothion (NOAEL = 12.5 mg/kg BW/day, LOAEL = 50 mg/kg BW/day based on tremors, ataxia, gait incapacitation, and other FOB parameters), an acute dietary risk assessment was not performed for the original HED RED Chapter because data to estimate single-day consumption of wheat gluten are not available. Rather, it was concluded that since the acute NOAEL is 100-fold greater than the NOAEL used to set the PAD, and calculations using the PAD indicate minimal chronic dietary risk, there is no concern for acute dietary exposure. However, using the average U.S. population exposure estimate (0.000026 mg/kg BW/day, based on revised tolerance level residues in wheat gluten), with the acute dietary NOAEL (12.5 mg/kgBW/day) results in an estimated acute dietary %PAD of 0.02%. Therefore, while there are uncertainties in the estimated risk due to uncertainties in the consumption estimate, this extremely low percent of acute population adjusted dose indicates that

risks from this use will be insignificant.

Exposure from Water
An assessment for the potential contamination of drinking water has been provided by EFED (Patricia D. Jennings to Chris Olinger, 11/7/97, attached). The review concluded the following: "Based on the proposed use of fenitrothion as roach, water bug, palmetto bug, and ant bait, releases of fenitrothion to ground water and surface water are not expected."

Residential Exposure
Exposures resulting from proper use of the ant and roach bait traps are expected to be insignificant. HED does not estimate risks for these types of uses because of the expected low potential for exposure. However as with other bait trap uses, the possibility of children acquiring these bait traps, which are placed around the home, and the possible oral exposure to the contents may exist. If this were to occur, a risk concern would exist for a child consuming the contents of a single bait station containing fenitrothion. Since this is a generic issue for bait stations for many pesticides, it will not be addressed further here. We note that for both of the bait station products, recent Notices of Pesticide Reregistration have been unconditionally issued (EPA Reg. No. 506-174 issued 7/17/97; EPA Reg. No. 506-175 issued 7/2/97).

Aggregate Assessment
Since exposure from residential uses and water are expected to be insignificant, an aggregate exposure assessment for fenitrothion would include consideration of exposures only from food.

Please let us know if further information is required.

Attachments:
Attachment 1: HED RED Chapter (John C. Redden, M.S. to Lois Rossi, 5/94)
Attachment 2: HIARC Report (Jess Rowland, 10/8/97, 2/23/98)
Attachment 3: Chronic Dietary Assessment (Christina Swartz, 5/19/99)
Attachment 4: Anticipated Residue Assessment (Christine Olinger, 5/19/99)
Attachment 5: Update to Consider FQPA Requirements (Michael Metzger, 2/28/98)
Attachment 6: Wheat Gluten Consumption and Australian Imports (Frank Hernandez 4/28/99).

cc: (without attachments) CLOlinger (RRB1), J. Dawson, Reg Std. File
7509C:CBRS:CLOlinger:clo:CM#2:Rm 816G:305-5406: 5/19/99
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